

**PATENT COOPERATION TREATY**  
**PCT**  
**INTERNATIONAL PRELIMINARY EXAMINATION REPORT**

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 484983 NJC/rlp	<b>FOR FURTHER ACTION</b>	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No.  PCT/NZ2003/000152	International Filing Date (day/month/year)  11 July 2003	Priority Date (day/month/year)  12 July 2002
International Patent Classification (IPC) or national classification and IPC  Int. Cl. <sup>7</sup> A61M 16/06		
Applicant  FISHER & PAYKEL HEALTHCARE LIMITED et al		

**Rec'd PCT/PTO 15 DEC 2004**

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 3 sheets, including this cover sheet.  
☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheet(s).

3. This report contains indications relating to the following items:

- I ☒ Basis of the report.
- II ☐ Priority.
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 9 February 2004	Date of completion of the report 20 October 2004
Name and mailing address of the IPEA/AU  AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer   <b>GEOFF SADLER</b> Telephone No. (02) 6283 2114

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## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/NZ200000152

**I. Basis of the report****1. With regard to the elements of the international application:\***

- ☒ the international application as originally filed.
- ☐ the description, pages , as originally filed,  
pages , filed with the demand,  
pages , received on with the letter of
- ☐ the claims, pages , as originally filed,  
pages , as amended (together with any statement) under Article 19, -  
pages , filed with the demand,  
pages , received on with the letter of
- ☐ the drawings, pages , as originally filed,  
pages , filed with the demand,  
pages , received on with the letter of
- ☐ the sequence listing part of the description:  
pages , as originally filed  
pages , filed with the demand  
pages , received on with the letter of

**2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.**

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

**3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:**

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

**4. ☐ The amendments have resulted in the cancellation of:**

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.

**5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\***

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

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## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International Application No.

PCT/NZ2003/000152

## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

## 1. Statement

Novelty (N)	Claims 3, 4, 6-12, 16, 17	YES
	Claims 1, 2, 5, 13-15	NO
Inventive step (IS)	Claims 3, 4, 6-12, 16, 17	YES
	Claims 1, 2, 5, 13-15	NO
Industrial applicability (IA)	Claims 1-17	YES
	Claims	NO

## 2. Citations and explanations (Rule 70.7)

The following documents identified in the International Search Report have been considered for the purposes of this report:

D1 - WO 2000/053265  
D2 - EP 1118346  
D3 - EP 1258266  
D4 - EP 1121953.

The claimed invention relates to a sealing interface or respiratory mask for use with the delivery of respiratory gases and is intended to provide improved comfort while maintaining a good face to mask seal and in particular it is intended to reduce dehydration of the oral cavity.

The solution according to claim 1 comprises an inner sealing member and outer sealing member which are adapted to seal around the facial contours of a user thereby providing a sealed fluid communication to the respiratory tract of said user, and said inner and outer sealing members are at least continuously in contact with each other around the facial contour contacting portions respectively.

Documents D1-D3 each disclose respiratory masks having an inner and outer sealing member. In particular: D1 has inner (11) and outer (10) sealing members which are in continuous contact see figures 1 and 2; D2 has inner (2) and outer (3) sealing member in continuous contact see figures 1 and 2; and, D3 has a plurality of sealing membranes which are in continuous contact see figures 6-9. Therefore the subject matter of claim 1 is not new and fails to meet the requirements of Article 33 PCT with regard to novelty and inventive step.

Furthermore, the features added by appended claims 2, 5, 13-15 relate only to features that are either known from D1-D3 or are typical in devices of this type and therefore they cannot be considered as contributing to patentable ingenuity.

Claims 3, 4, 6-12, 16, 17 include features which are not disclosed in any of the documents D1-D4 and therefore the subject matter of these claims is new and meets the requirements of Article 33(2) PCT with regard to novelty.

Furthermore claims 3, 4, 6-12, 16, 17 are not obvious in the light of any of the cited documents nor are they disclosed in any obvious combination of them. It is also considered that it would not be obvious to a person skilled in the art in the light of common general knowledge either by itself or in combination with any of these documents.

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